

Peralatan anestesi dan pernapasan - Dimensi *non interchangeable screw-threaded*(NIST) konektor tekanan rendah untuk gas medis

(ISO 18082:2014, IDT, Eng)

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Prakata

Standar Nasional Indonesia (SNI) ISO 18082:2014, dengan judul *Peralatan anestesi dan pernapasan - Dimensi non interchangeable screw-threaded (NIST) konektor tekanan rendah untuk gas medis (ISO 18082:2014, IDT)*, merupakan hasil adopsi identik dari standar ISO 18082:2014 *Anaesthetic and respiratory equipment — Dimensions of noninterchangeable screw threaded (NIST) low pressure connectors for medical gases*, dengan metode republikasi *reprint*, yang ditetapkan oleh BSN pada tahun 2020.

Standar ini disusun oleh Komite Teknis 11-03 Alat Kesehatan Elektromedik dengan Badan Standardisasi Nasional (BSN) sebagai sekretariat Komite Teknis. Standar ini telah dibahas dalam rapat teknis, dan terakhir disepakati dalam rapat konsensus di Jakarta pada tanggal 20 April 2020 yang dihadiri oleh para pemangku kepentingan (*stakeholder*) terkait, yaitu perwakilan dari produsen, konsumen, pakar dan pemerintah, serta perwakilan dari lembaga penguji, asosiasi, perguruan tinggi, pakar serta instansi terkait.

Standar ini telah melalui tahap jajak pendapat pada tanggal 18 Mei 2020 sampai dengan 6 Juni 2020 dengan hasil akhir disetujui menjadi SNI.

Apabila di kemudian hari pengguna menemukan kesulitan dalam penggunaan standar ini, maka dianjurkan untuk merujuk pada standar aslinya yaitu ISO 18082:2014 dan/atau dokumen terkait lain yang menyertainya.

Perlu diperhatikan bahwa kemungkinan beberapa unsur dari dokumen standar ini dapat berupa hak paten. Badan Standardisasi Nasional tidak bertanggungjawab untuk pengidentifikasian salah satu atau seluruh hak paten yang ada.

Introduction

This International Standard has been prepared in response to the need for a safe method of connecting medical equipment intended to administer medical gases to patients or power medical devices. Medical gases are stored in cylinders or cryogenic vessels, or can be produced on site; several medical devices (e.g. pressure regulators, hose assemblies, flow-metering devices, lung ventilators, anaesthetic workstations) can be fitted between the source of supply and the medical device. At each interface gas-specific connectors are needed to ensure that the intended medical gas is administered to the patient.

While the desirability of achieving agreement on a single International Standard for screw-threaded connectors has never been in doubt, the present pattern of usage has made such agreement impossible.

Nevertheless, fears that proliferation of individual national standards or practices will eventually result in potentially dangerous cross-connection between components for different gases have led to the choice of several different connector systems, all of which are intended to be incompatible with each other.

This International Standard specifies the dimensions and the allocation of non-interchangeable screw threaded (NIST) connectors for use with medical gases.

This International Standard does not specify the dimensions and the allocation of

- diameter index safety system (DISS) connectors specified in CGA V-5^[9],
- sleeve indexed system (SIS) connectors specified in AS 2896^[7], and
- quick connectors designed for terminal units specified in ISO 9170-1

Peralatan anestesi dan pernapasan - Dimensi *non interchangeable screw-threaded* (NIST) konektor tekanan rendah untuk gas medis

1 Scope

1.1 This International Standard specifies the dimensions, the allocation and marking of non-interchangeable screw-threaded (NIST) connectors intended to be used at operating pressures up to 1 400 kPa, and for vacuum systems at pressures not greater than 60 kPa absolute.

1.2 This International Standard specifies NIST connectors intended for use with the following medical gases:

- oxygen;
- nitrous oxide;
- medical air;
- helium;
- carbon dioxide;
- xenon;
- specified mixtures of the gases listed above;
- oxygen-enriched air;
- air for driving surgical tools;
- nitrogen for driving surgical tools;

and for use with vacuum.

NOTE Low-pressure hose assemblies for medical gases and vacuum are specified in ISO 5359^[3].

1.3 The information to be supplied by the manufacturer is excluded from the scope of this International Standard because information about the use of NIST connectors is supplied by the manufacturer of each medical device to which the connectors are permanently fitted.

NOTE Environmental aspects are dealt with in each International Standard concerning medical devices fitted with NIST connectors.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1

gas-specific

having characteristics which prevent connections between different gas services

[SOURCE: ISO 7396-1:2007, 3.14]

2.2

medical gas

any gas or mixture of gases intended for administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

[SOURCE: ISO 4135:2001, 1.1.1]

2.3

non-interchangeable screw-threaded connector

NIST connector

range of male and female components intended to maintain gas specificity by the allocation of a set of different diameters and a left- or right-hand screw thread to the mating components for each particular gas

[SOURCE: ISO 9170-1:2008, 3.10]

3 Dimensions and allocation of NIST connectors

The dimensions of the NIST body, nipple and nut shall comply with Figures 1, 2, 3 and 4 and Tables 2, 3 and 4.

Allocation of NIST connectors shall comply with Table 1.

Compliance shall be verified by measurement and visual inspection.

Table 1 — NIST connector allocation — Right-hand thread

Connector reference	Gas
A1	Medical air/oxygen mixture
A2	Oxygen/nitrous oxide mixture [$O_2 = 50\%$ (volume fraction)]
A3	Medical air
A4	Nitrous oxide
A5	Nitrous oxide/oxygen mixtures [$N_2O < 80\%$ (volume fraction)]
A6	Air for driving surgical tools
A7	Not allocated
A8	Oxygen
A9	Not allocated
A10	Vacuum
B11	Carbon dioxide
B12	Oxygen-enriched air
B13	Oxygen/carbon dioxide mixture [$CO_2 \leq 7\%$ (volume fraction)]
B14	Helium/oxygen mixture [$He \leq 80\%$ (volume fraction)]
B15	Helium/oxygen mixture [$O_2 < 20\%$ (volume fraction)]
B16	Xenon
B17	Special gas mixture
B18	Nitrogen for driving surgical tools
C19	Carbon dioxide/oxygen mixture [$CO_2 > 7\%$ (volume fraction)]
C20	Helium
C21	Medical air/helium/carbon monoxide [$CO < 1\%$ (volume fraction)]
C22	Not allocated
C23	Not allocated
C24	Not allocated
NOTE Left-hand threads have not been allocated.	

Table 2 — Indexing diameters including tolerances for NIST body (see Figure 1)

Dimensions in millimetres

Connector reference	Dimension <i>B</i>	Dimension <i>C</i>	Dimension <i>D</i>
A1	8	12,5 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$	17
A2	8,5		16,5
A3	9 $\begin{smallmatrix} +0,09 \\ 0 \end{smallmatrix}$		16
A4	9,5		15,5
A5	10		15 $\begin{smallmatrix} +0,11 \\ 0 \end{smallmatrix}$
A6	10,5		14,5
A7	11 $\begin{smallmatrix} +0,11 \\ 0 \end{smallmatrix}$		14
A8	11,5		13,5
A9	12		13
A10	12,5 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$		12,5 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$
B11	7,5	11 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$	14,5
B12	8		14
B13	8,5 $\begin{smallmatrix} +0,09 \\ 0 \end{smallmatrix}$		13,5 $\begin{smallmatrix} +0,11 \\ 0 \end{smallmatrix}$
B14	9		13
B15	9,5		12,5
B16	10		12
B17	10,5 $\begin{smallmatrix} +0,11 \\ 0 \end{smallmatrix}$		11,5
B18	11 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$		11 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$
C19	7,5	10 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$	12,5
C20	8 $\begin{smallmatrix} +0,09 \\ 0 \end{smallmatrix}$		12 $\begin{smallmatrix} +0,11 \\ 0 \end{smallmatrix}$
C21	8,5		11,5
C22	9		11
C23	9,5		10,5
C24	10 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$		10 $\begin{smallmatrix} +0,043 \\ 0 \end{smallmatrix}$

Table 3 — Indexing diameters including tolerances for NIST nipple (see Figure 2)

Dimensions in millimetres

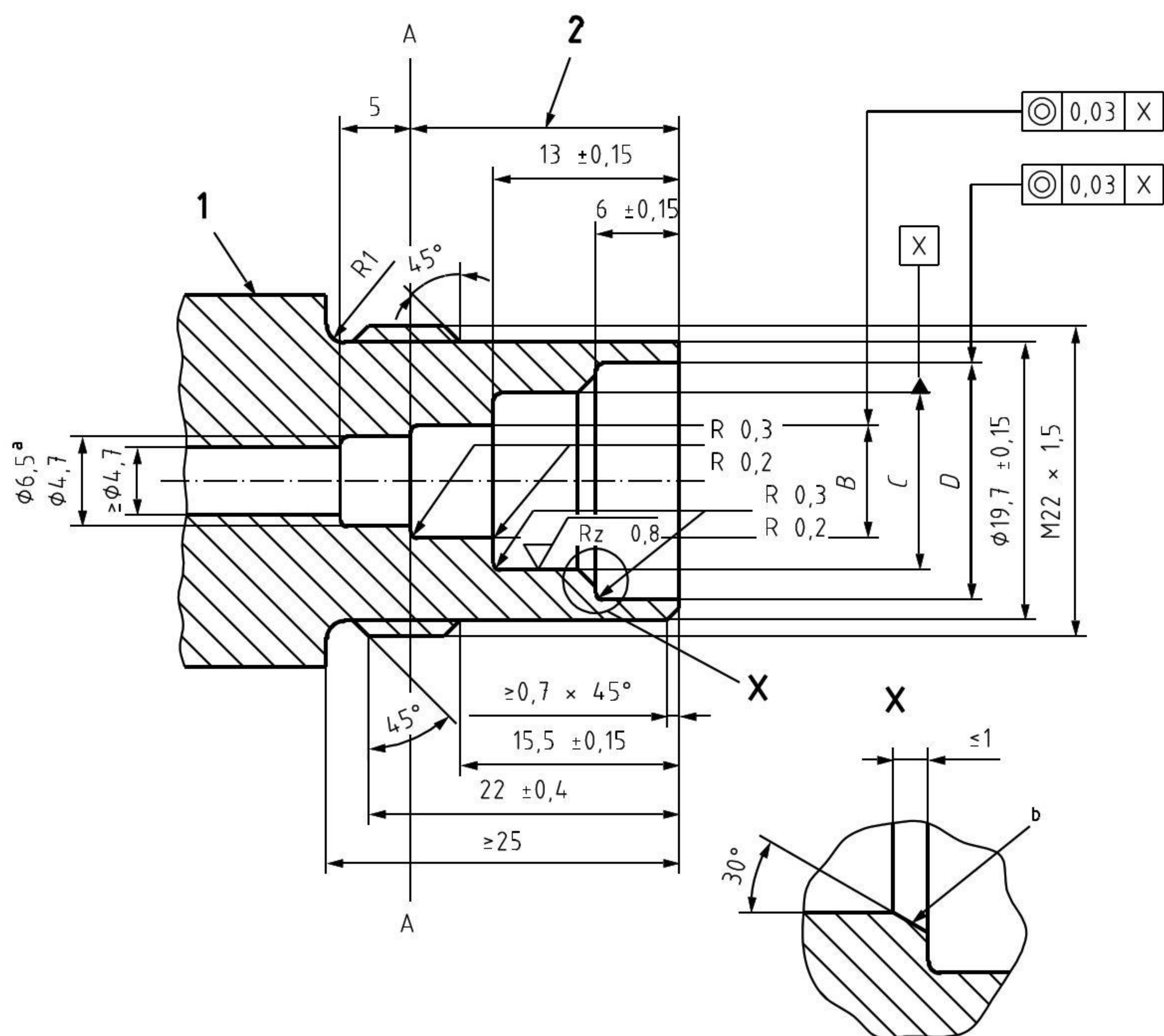
Connector reference	Dimension <i>E</i>	Dimension <i>F</i>	Dimension <i>G</i>	Dimension <i>H</i>	Dimension <i>I</i>
A1	17	12,5 −0,05 −0,16	8	8,5 0 −0,10	3,3 0 −0,20
A2	16,5		8,5 −0,04 −0,13		
A3	16		9		
A4	15,5		9,5		
A5	15		10		
A6	14,5		10,5		
A7	14		11		
A8	13,5		11,5 −0,05 −0,16		
A9	13		12		
A10	12,5		12,5		
B11	14,5 −0,05 −0,16	11 −0,05 −0,16	7,5	8,3 0 −0,10	
B12	14		8		
B13	13,5		8,5		
B14	13		9		
B15	12,5		9,5 −0,04 −0,13		
B16	12		10		
B17	11,5		10,5		
B18	11		11 −0,05 −0,16		2,5 0 −0,20
C19	12,5	10 −0,04 −0,13	7,5	7,3 0 −0,10	
C20	12		8		
C21	11,5		8,5 −0,04 −0,13		
C22	11		9		
C23	10,5		9,5		
C24	10		10		


Table 4 — Dimensions of “O” rings

Dimensions in millimetres

Connector reference range	Internal diameter	Internal diameter tolerance	Section diameter	Section diameter tolerance
A	7,6	$\pm 0,15$	2,4	$\pm 0,08$
B	8,1	$\pm 0,15$	1,6	$\pm 0,08$
C	7,1	$\pm 0,15$	1,6	$\pm 0,08$
<p>NOTE 1 Recommended hardness 75° IRHD (International Rubber Hardness Degrees, see ISO 48).</p> <p>NOTE 2 These dimensions are based upon BS 4518^[8]. For A, B and C ranges the “O” rings are identified in BS 4518 with the reference numbers 0076–24, 0081–16 and 0071–16 respectively.</p>				

Dimensions in millimetres



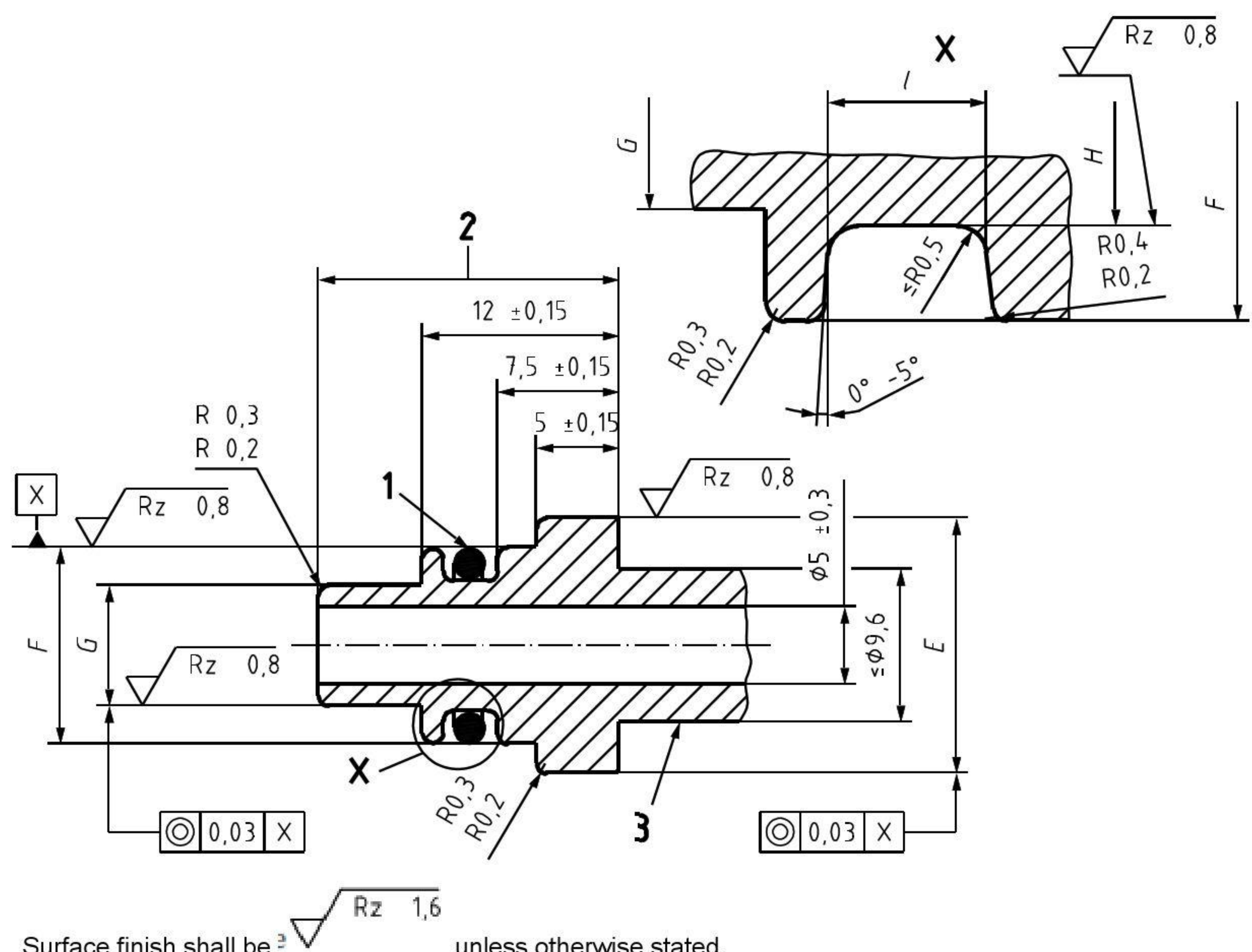
Surface finish shall be  unless otherwise stated.

Key

- 1 position for marking gas identification symbol
- 2 A range = $19 \pm 0,15$; B range = $25 \pm 0,15$; C range = $31 \pm 0,15$
 - a Diameters 6,5 and 4,7 and the location of face AA are critical. If this face is movable, for example when it forms part of a check valve, it is essential that means are provided to prevent its movement to a depth greater than 19 mm/25 mm/31 mm. See Table 2 for dimensions *B*, *C* and *D*.
 - b For connectors number A10, B18 and C24, the 12,5 mm/11 mm/10 mm diameters extend over the full depths of 19 mm/25 mm/31 mm respectively and this chamfer will appear at the nose of the fitting.

Figure 1—NIST body

Dimensions in millimetres



Surface finish shall be $\sqrt{Rz\ 1,6}$ unless otherwise stated.

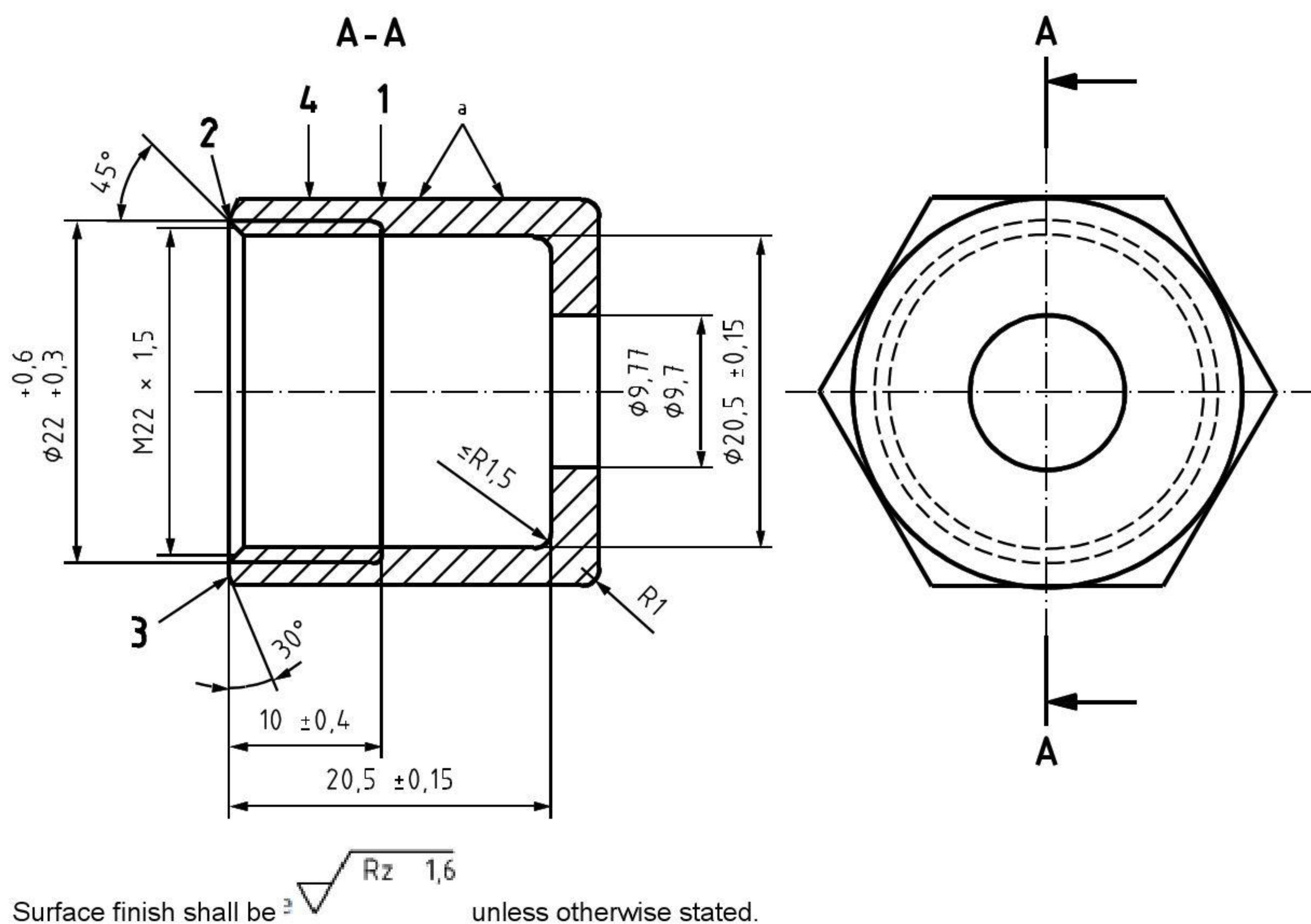
Key

- 1 "O" ring (dimensions given in Table 4)
- 2 A range: 18,5 ± 0,15, use "O" ring No 0076-24
B range: 24,5 ± 0,15, use "O" ring No 0081-16
C range: 30,5 ± 0,15, use "O" ring No 0071-16
- 3 position for marking gas identification symbol

NOTE Gas tightness and smooth operation are best achieved when the "O" ring is compressed between 0,66 mm and 0,19 mm in diameter under maximum and minimum tolerancing conditions. See Table 3 for dimensions E, F, G, H and I.

Figure 2—NIST nipple

Dimensions in millimetres

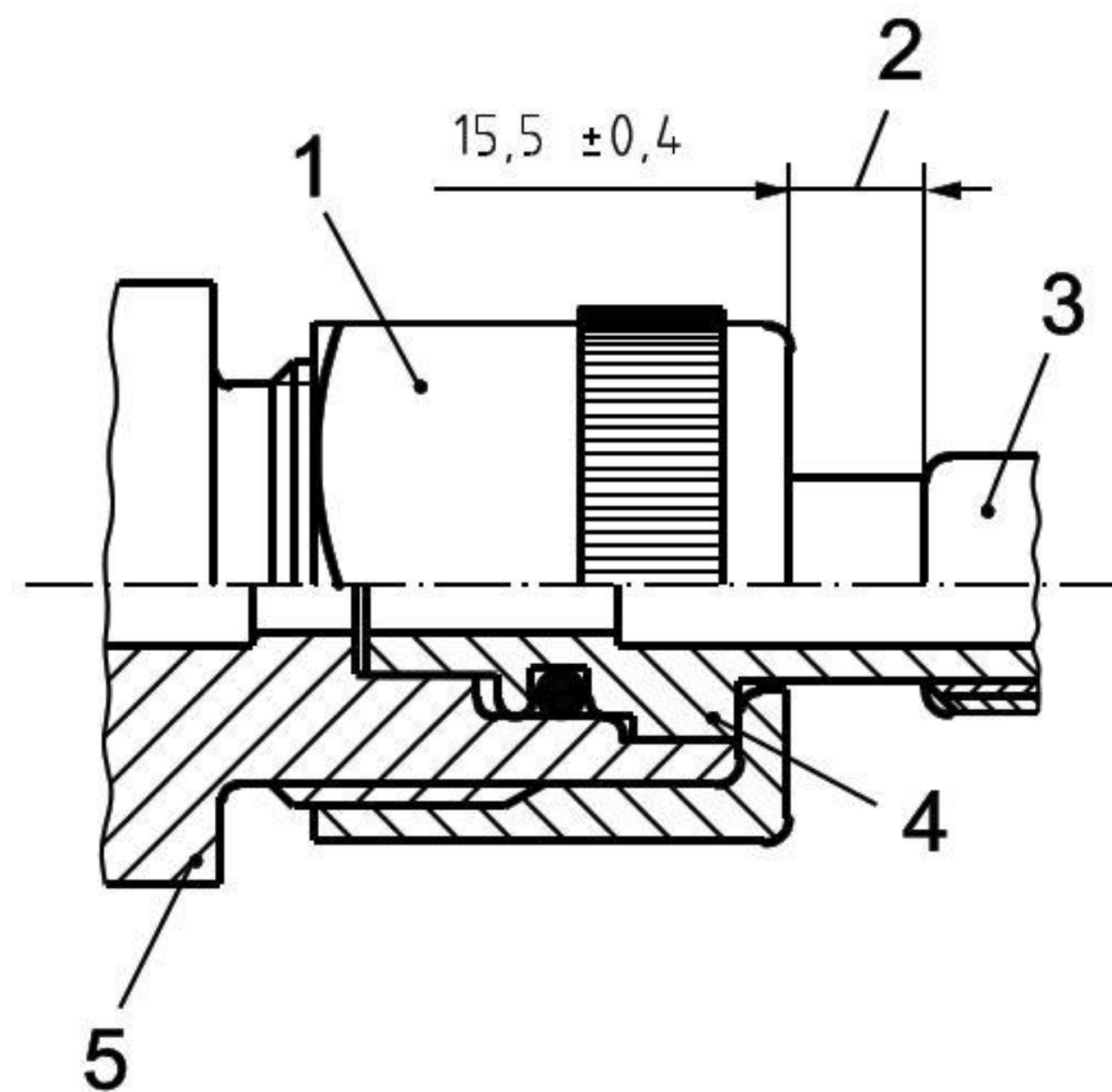
**Key**

- 1 notch with Vee across corners of hexagon to depth of flat for identification of left hand nuts only
- 2 chamfer to root of the thread
- 3 external chamfer
- 4 position for marking gas identification symbol
- a This area should preferably be knurled.

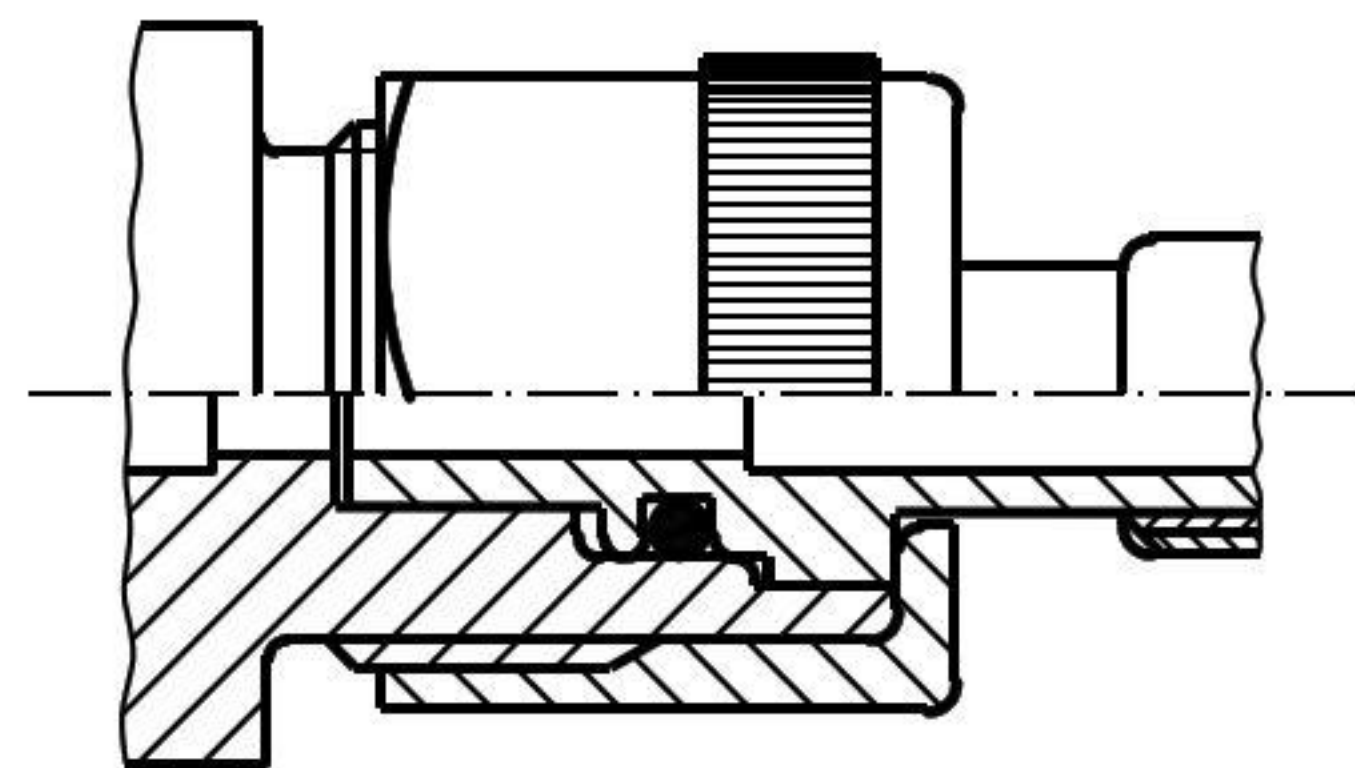
NOTE External shape and dimensions can be varied to suit the materials used

Figure 3—NIST nut

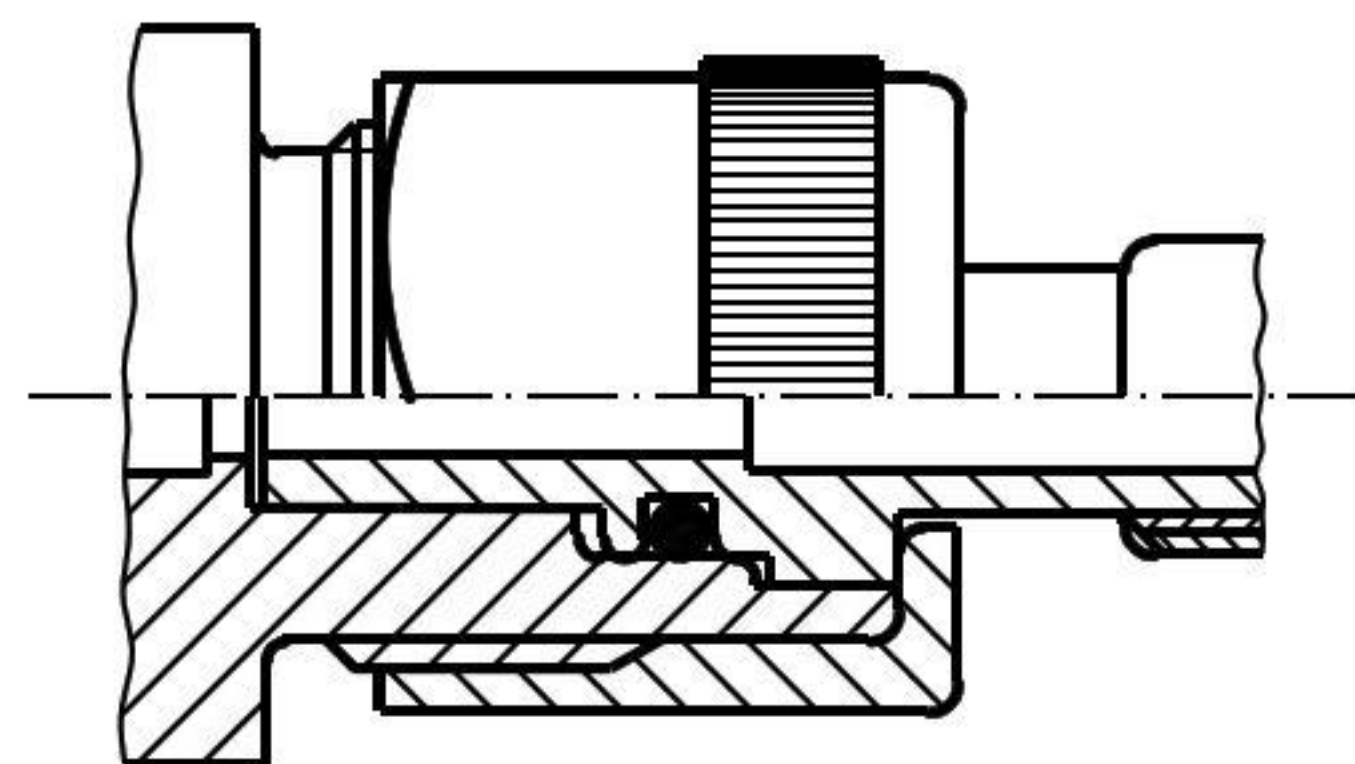
Dimensions in millimetres



a) A range



b) B range



c) C range

Key

- 1 NIST nut (see Figure 3)
- 2 free motion area
- 3 ferrule or hose fixing device
- 4 NIST nipple (see Figure 2)
- 5 NIST body (see Figure 1)

NOTE Dimension 15,5 mm to allow access to "O"-ring on nipple.

Figure 4 — NIST assembly

4 Marking

The connectors shall be durably and legibly marked with the symbol of the relevant gas in accordance with Table 5.

NOTE In addition to the symbol, the name of the gas may be used.

Check compliance for durability of markings by the test given in Clause 5.

The marking shall be legible to a person having visual acuity (corrected if necessary) of 1 standing 0,5 m from the connector at an illuminance of 215 lux.

5 Test for durability of markings

Rub the markings by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit and then for 15 s with a cloth rag soaked with isopropyl alcohol. Carry out these tests at ambient temperature. Verify that the markings are still legible.

Table 5 — Marking

Medical gas or mixture	Symbol
Oxygen	O ₂
Oxygen-enriched air	^a
Nitrous oxide	N ₂ O
Oxygen/nitrous oxide mixture [O ₂ = 50 % (volume fraction)]	O ₂ /N ₂ O
Nitrous oxide/oxygen mixtures [N ₂ O < 80 % (volume fraction)]	N ₂ O/O ₂ ^b
Medical air	Air ^c
Air for driving surgical tools	Air – 800 ^c
Vacuum	Vac ^c
Air/oxygen mixture	Air/O ₂ ^c
Nitrogen for driving surgical tools	N ₂ - 800
Helium	He
Helium/oxygen mixture [O ₂ < 20 % (volume fraction)]	He/O ₂
Helium/oxygen mixture [He ≤ 80 % (volume fraction)]	O ₂ /He
Oxygen/carbon dioxide mixture [CO ₂ ≤ 7 % (volume fraction)]	O ₂ /CO ₂
Carbon dioxide	CO ₂
Carbon dioxide/oxygen mixture [CO ₂ > 7 % (volume fraction)]	CO ₂ /O ₂
Xenon	Xe
Medical air/helium/carbon monoxide [CO < 1 % (volume fraction)]	LFT ^d
Special gas mixture	^e
^a To be defined by national authorities. ^b Except for oxygen/nitrous oxide mixtures [O ₂ = 50 % (volume fraction)]. ^c National languages may be used for air and vacuum. ^d Lung function test. ^e For limited experimental applications. Symbols for special gas mixtures should conform to the chemical symbols of the components.	

Bibliography

- [1] ISO 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*
- [2] ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*
- [3] ISO 5359, *Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases*¹
- [4] ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*
- [5] ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*
- [6] ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*
- [7] AS 2896:1998, *Medical gas systems - Installations and testing of non flammable medical gas pipeline systems*
- [8] BS 4518, *Specification for metric dimensions of toroidal sealing rings ("O" rings) and their housings*
- [9] CGA V-5, *Diameter Index Safety System (Non-Interchangeable Low Pressure Connections for Medical Gas Applications)*²

¹ To be published. Revision of ISO 5359:2008 and ISO 5359:2008/Amd.1:2011.

² Compressed Gas Association Inc. (CGA), 1725 Jefferson Davis Highway, Arlington, VA 22202, USA.

Informasi pendukung terkait perumus standar

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